IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

ROQUETTE FRERES,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 06-540-MPT
	)	
SPI PHARMA, INC., *et al.*	)	
	)	
Defendants.	)	

DEFENDANT SPI PHARMA, INC.'S MOTION FOR LEAVE TO AMEND ITS ANSWER, DEFENSES AND COUNTERCLAIMS PURSUANT TO FED. R. CIV. P. 15(a)

Defendant SPI Pharma, Inc. ("SPI") respectfully moves this Court pursuant to Fed. R. Civ. P. 15(a) and Local Rule 15.1 for leave to Amend SPI's Answer, Defenses and Counterclaims to Plaintiff's Second Amended Complaint, filed on July 13, 2007. A copy of SPI's proposed Amended Answer, Defenses and Counterclaims to Plaintiff's Second Amended Complaint ("Answer") is attached as Exhibit A. A black-lined version of SPI's Answer showing all of the proposed changes is attached as Exhibit B. Pursuant to Local Rule 7.1.1, counsel for SPI certifies that a reasonable effort has been made to obtain plaintiff Roquette Freres' consent to the amendment. For the reasons set forth in the Memorandum filed herewith, SPI requests that the Court grant leave to SPI to amend its Answer to add:

1. An affirmative defense of unenforceability of U.S. Patent No. 5,573,777 ("the '777 patent") due to inequitable conduct by applicants, Plaintiff, and/or its agents or representatives (collectively, "Applicants") to procure issuance of the '777 patent.

2. A counterclaim for declaratory judgment of unenforceability of the '777 patent due to inequitable conduct by Applicants to procure issuance of the '777 patent.

YOUNG CONAWAY STARGATT
& TAYLOR, LLP

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New York, New York 10178
(212) 309-6000

Dated: December 28, 2007

CERTIFICATE OF SERVICE

I, Jeffrey T. Castellano, hereby certify that on December 28, 2007, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

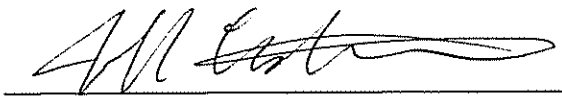
Mary B. Graham, Esquire
Julia Heaney, Esquire
Morris, Nichols, Arsht & Tunnell LLP
1201 North Market Street
Wilmington, DE 19801

I further certify that on December 28, 2007, I caused a copy of the foregoing document to be served by hand delivery and e-mail on the above-listed counsel of record and on the following in the manner indicated:

BY E-MAIL

Douglas V. Rigler, Esquire
Young & Thompson
745 South 23rd Street, Suite 200
Arlington, VA 22202

YOUNG CONAWAY STARGATT & TAYLOR, LLP



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Attorneys for Defendants

IN THE UNITED STATES DISTRICT COURT

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Plaintiff,	)	
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v.	)	C.A. No. 06-540-MPT
	)	
SPI PHARMA, INC., *et al.*	)	
	)	
Defendants.	)	

ORDER

At Wilmington this ___ day of _____, 200__, IT IS HEREBY ORDERED that defendant SPI Pharma, Inc.'s Motion for Leave to Amend its Answer, Defenses, and Counterclaims is GRANTED. Plaintiff's proposed First Amended Answer, Defenses and Counterclaims in Response to Plaintiff's Second Amended Complaint, in the form attached as Exhibit A to this motion, shall be deemed filed and served as of the date of this order.

_____
United States District Judge

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

ROQUETTE FRERES,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 06-540-MPT
	)	
SPI PHARMA, INC., *et al.*	)	**DEMAND FOR JURY TRIAL**
	)	
Defendants.	)	

DEFENDANT SPI PHARMA, INC.'S FIRST AMENDED ANSWER, DEFENSES AND COUNTERCLAIMS IN RESPONSE TO PLAINTIFF'S SECOND AMENDED COMPLAINT

Defendant, SPI Pharma, Inc. ("SPI Pharma"), by and through the undersigned counsel requests trial by jury on all issues so triable, and amends its Answers to the corresponding paragraphs of the Second Amended Complaint ("Complaint") of Plaintiff, Roquette Freres ("Plaintiff" or "Roquette"), as follows:

JURISDICTION AND VENUE

1. SPI Pharma admits that the complaint, on its face, alleges a cause of action for patent infringement arising under Title 35 of the United States Code, that jurisdiction of this Court is conferred by 28 U.S.C. § 1338(a), that venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b) and that it has a principal place of business in the District of Delaware. SPI Pharma denies the remaining allegations of Paragraph 1 of the Complaint and specifically denies that it has engaged in infringing activities within this District.

BACKGROUND AND PARTIES

2. SPI Pharma admits the allegations of Paragraph 2 of the Complaint.

3. SPI Pharma admits that U.S. Patent No. 5,573,777 (the " '777 patent"), on its face, lists Plaintiff as the assignee, and that a copy of the '777 patent is attached to the Complaint as Exhibit A. SPI Pharma otherwise has insufficient knowledge or information upon which to form a belief as to the truth of the remaining allegations and therefore denies them.

4. SPI Pharma admits the allegations of Paragraph 4 of the Complaint.

5. SPI Pharma has insufficient knowledge or information upon which to form a belief as to the truth of the allegations of Paragraph of 5 of the Complaint and therefore denies them and leaves Plaintiff to its proof.

6. SPI Pharma has insufficient knowledge or information upon which to form a belief as to the truth of the allegations of Paragraph of 6 of the Complaint and therefore denies them and leaves Plaintiff to its proof.

7. SPI Pharma has insufficient knowledge or information upon which to form a belief as to the truth of the allegations of Paragraph of 7 of the Complaint and therefore denies them and leaves Plaintiff to its proof.

INFRINGEMENT OF THE '777 PATENT

8. SPI Pharma denies the allegations contained in Paragraph 8 of the Complaint.

9. SPI Pharma denies the allegations contained in Paragraph 9 of the Complaint.

10. SPI Pharma denies the allegations contained in Paragraph 10 of the Complaint.

11. SPI Pharma has insufficient knowledge or information upon which to form a belief as to the truth of the allegations of Paragraph of 11 of the Complaint and therefore denies them and leaves Plaintiff to its proof.

12. SPI Pharma has insufficient knowledge or information upon which to form a belief as to the truth of the allegations of Paragraph of 12 of the Complaint and therefore denies them and leaves Plaintiff to its proof.

13. SPI Pharma denies the allegations contained in Paragraph 13 of the Complaint.

14. SPI Pharma admits that it sells and has been selling its MANNOGEM™ EZ Spray Dried Mannitol product in the United States. SPI Pharma denies the remainder of the allegations contained in Paragraph 14.

15. SPI Pharma denies the allegations contained in Paragraph 15 of the Complaint.

16. SPI Pharma admits that on or about September 3, 2004, it received a letter from Plaintiff asserting a claim for infringement of the '777 patent, but otherwise denies the remaining allegations of Paragraph 16 of the Complaint.

17. SPI Pharma denies the allegations contained in Paragraph 17 of the Complaint.

DEFENSES and AFFIRMATIVE DEFENSES

SPI Pharma asserts the following defenses and affirmative defenses against the allegations made by Plaintiff in the Complaint. SPI Pharma hereby reserves the right to amend its First Amended Answer and plead any additional defenses and/or counterclaims that become available or known as this action proceeds, including, but not limited to, those defenses that become known to SPI Pharma through discovery.

First Defense

18. SPI Pharma does not infringe any valid claim of the '777 patent, nor does SPI Pharma contribute to or induce infringement of any valid claim of the '777 patent.

Second (Affirmative) Defense

19. The '777 patent is invalid for failure to satisfy the conditions of patentability specified in Title 35, U.S.C. §§ 101, 102, 103 and 112.

Third (Affirmative) Defense

20. Plaintiff's claims are barred, in whole or part, by laches.

Fourth (Affirmative) Defense

21. Plaintiff's claims are barred, in whole or part, by equitable estoppel.

Fifth (Affirmative) Defense

22. The '777 patent is unenforceable as procured through inequitable conduct. In violation of their duty of candor to the United States Patent and Trademark Office ("PTO"), applicants, Plaintiff, and/or its agents or representatives (collectively, "Applicants") knowingly and intentionally misled the PTO concerning the content of the prior art described in the '777 patent specification, and mischaracterized and withheld material information in connection with the comparative data presented in Examples 2 and 3, and associated tables, in the '777 patent specification.

COUNTERCLAIMS

For its counterclaims against Plaintiff, SPI Pharma alleges as follows:

Nature of the Counterclaim

23. The counterclaims herein are made under 28 U.S.C. §§ 2201 and 2202 for a declaratory judgment of invalidity and non-infringement of the '777 patent.

24. This Court has jurisdiction over the subject matter of these counterclaims under 28 U.S.C. §§ 1331 and 1338 in that the actions arise under the Patent Laws of the United States, Title 35, United States Code. Venue is proper under 28 U.S.C. § 1391 and Plaintiff has submitted itself to the jurisdiction of this Court.

25. Plaintiff and Counterclaim-Defendant Roquette is a corporation formed under the laws of France with its principal place of business at 62080 Lestrem, Cedex, France.

26. Defendant and Counterclaim-Plaintiff SPI Pharma is a Delaware corporation with its principal place of business at 321 Cherry Lane, New Castle, Delaware.

27. An actual and justiciable controversy exists between Plaintiff and SPI Pharma concerning the invalidity and non-infringement of the '777 patent.

First Counterclaim

28. The claims of the '777 patent are invalid for failure to satisfy the conditions of patentability specified in Title 35, U.S.C. §§ 101, 102, 103 and 112.

Second Counterclaim

29. SPI Pharma does not infringe any valid claim of the '777 patent, nor does SPI Pharma contribute to or induce infringement of any valid claim of the '777 patent.

Third Counterclaim

30. The '777 patent is unenforceable as procured through inequitable conduct. In violation of their duty of candor to the PTO, Applicants knowingly and intentionally misled the PTO concerning the content of the prior art described in the '777 patent specification, and mischaracterized and withheld material information in connection with the comparative data presented in Examples 2 and 3, and associated tables, in the '777 patent specification.

Applicants Misrepresented the Content of the Prior Art

31. The '777 patent specification contains descriptions of several prior art patents and references. See '777 Patent, Col. 1, ln. 14 – Col. 4, ln. 30.

32. For example, the '777 patent specification describes prior art reference Japanese Patent Application 61-85331 ("JP 61-85331"), which is directed toward a method for preparing a mixture of D-mannitol with starch hydrolysate, by spray-drying, to obtain an excipient for tabletting. In describing JP 61-85331, the '777 patent specification states: "It emerges from this document that, with less than 5% starch hydrolysate, the excipient obtained according to this process,...always has an excessively high content of particles with a size of less than 200 mesh (75 microns)." (emphasis added).

33. JP 61-85331 contains data that include, *inter alia*, particle size distribution percentages for four samples of the excipient obtained according to the method described therein. These data show that the samples had only between 4-6% of particles with a size of less than 200 mesh (75 microns) -- not an "excessively high content" as Applicants represented to the PTO in the '777 patent specification.

34. Inventors Serpelloni and Boonaert testified at deposition that they did not review JP-6185530, despite making factual assertions concerning that reference in the '777 patent specification.

35. The '777 patent specification also describes prior art reference Japanese Patent Application 61-85330 ("JP 61-85330"), which is directed toward a method for preparing D-mannitol (without starch hydrolysate), by spray drying, to obtain an excipient for tabletting. In describing JP 61-85330, the '777 patent specification states: "It appears that the products obtained under these conditions contain, in the manner of the control products, more than 50% of

particles with a size of less than 200 mesh (75 microns), which is harmful to a correct flow of the products." (emphasis added).

36. JP 61-85330 contains data that include, *inter alia*, particle size distribution percentages for two samples of the excipient obtained according to the method described therein. These data show that the samples had only between 7-8% of particles with a size of less than 200 mesh (75 microns) -- not more than 50% as Applicants represented to the PTO in the '777 patent specification.

37. The '777 patent specification also describes prior art reference Japanese Patent 55-36646 ("JP 55-36646"), which is directed toward a method for producing a granular crystalline sugar alcohol, such as mannitol, by spray drying. In describing JP 55-36646, the '777 patent specification states: "Moreover, the product obtained always contains a very high content of fine particles, like the product described in Japanese Patent Application JP 61-85330." (emphasis added).

38. JP 55-36646 does not contain any data reflecting particle size distribution percentages nor statements concerning the percentage of fine particles obtained by the process described therein.

39. Inventor Boonaert testified at deposition that he did not verify the statement in the '777 patent specification concerning JP 55-36646.

40. The '777 patent specification describes prior art reference U.S. Patent No. 3,145,146 ("the '146 patent"), which is directed to the modification of the physical characteristics of mannitol by spray drying. In describing the '46 patent, the '777 patent specification states: "It has been verified that the size of the particles according to this process [i.e., the '146 patent] is, just as with JP 80 [sic – 55]-36646 and JP 61-85330 processes described

above, always very low, so much so that the mean diameter of the particles is between 50 and 75 microns." (emphasis added).

41. The '146 patent does not contain any data or statements relating to the mean diameter of the particles obtained according to the process described therein.

42. Inventors Serpelloni and Boonaert testified at deposition that they were not familiar with the '146 patent or had never reviewed it, despite making factual assertions concerning that reference in the '777 patent specification. Inventor Boonaert testified that he did not verify the statement in the '777 patent specification concerning the '146 patent.

Applicants Presented Misleading, Incomplete and Unsupported Data in the '777 Patent Specification

43. Applicants provide two tables of data in the '777 patent specification that purport to compare functional properties of mannitol obtained in accordance with the alleged invention to products obtained in accordance with the prior art ("prior art products"). See Table in Example 2, Col. 11 and 12, lns. 1-40 (hereinafter "Table 1") and Table in Example 3, Col. 12, lns. 46-53 (hereinafter "Table 2").

44. Table 1 provides data for five comparator prior art products. Only one of the comparators is a spray-dried mannitol. The other four comparators are mannitol products produced by means other than spray drying. Applicants did not provide any data in Table 1 for closer prior art comparators such as mannitol obtained in accordance with JP-55-36646 or the '146 patent, which are both directed to spray-dried mannitol, despite being aware of these references and describing them in an earlier portion of the '777 patent specification. (See Paragraphs 37 and 40, *supra*).

45. Inventor Serpelloni testified at deposition that he did not conduct any of the tests resulting in the data provided in Table 1, nor did he ever see any documentation to support those

data. With respect to Table 1, inventor Boonaert testified at deposition that "the only possible test that we could carry out in production [dept] was density and the diameter of particles," but he never claimed that he actually performed those test. To date, Roquette has not produced any documents that record the data provided in Table 1.

46. On its face, Table 1 data are inconsistent, incomplete and/or contradictory. For example, while some data show a range of values, suggesting that Applicants performed multiple experiments, others show only a single value, suggesting that Applicants performed only a single experiment. If Applicants performed multiple experiments, then they intentionally omitted data in those instances where they reported a single data point rather than a range. Alternatively, if Applicants performed a single experiment, then where they reported a range of values, they intentionally used data from a different source without proper attribution or notice to the PTO.

47. In addition, Table 1 purports to provide data for the "Commercial Product" produced according to French Patent No. 2,572,045 ("the '045 patent"), a prior art patent issued to Serpelloni and assigned to Roquette. However, Serpelloni testified at deposition that Roquette never made a commercial product according to the process in the '045 patent and that he did not know the identity of the product that was allegedly tested.

48. Table 2 in the '777 patent specification compares the compression force of mannitol made in accordance with the alleged invention to the compression force of granulated sucrose, lactose monohydrate in the α form, lactose monohydrate in the a form (atomized), and anhydrous lactose in the α form. Table 2, Col. 12, lns. 46-67. Applicants do not compare mannitol made in accordance with the alleged invention with any prior art mannitol product, even though such products were readily available. The data in Table 2 purport to show that the "product according to the invention permits the advantageous obtention [sic] of harder tablets

than with the different compressible products based on lactose or on sucrose currently utilized in this application." '777 patent, Col. 12, lns. 54-57.

49. Data for compression force for prior art mannitol products was readily available to Applicants because Roquette, and inventor Serpelloni in particular, had conducted such tests during manufacture of its own prior art granular mannitol product. Those data show that there is no difference between the alleged invention and prior art mannitol with respect to compression force.

50. The data and comparisons in Table 2 are misleading because they do not utilize the closest prior art. Applicants intentionally withheld information material to patentability with respect to compression force in order to exaggerate the alleged benefits of their invention to the PTO.

51. The foregoing facts and circumstances set forth in this Third Counterclaim constitute inequitable conduct on the part of Applicants rendering the '777 patent unenforceable.

WHEREFORE, Defendant and Counterclaim-Plaintiff SPI Pharma asks that the Court enter an Order against Plaintiff and Counterclaim-Defendant Roquette as follows:

i. That the Complaint be dismissed with prejudice, that Roquette take nothing by way of its Complaint and that SPI Pharma be awarded judgment in its favor on the claims in Roquette's Complaint;

ii. That the Court declare, adjudge and decree that the claims of the '777 patent are invalid;

iii. That the Court declare, adjudge and decree that SPI Pharma has not infringed and does not infringe any valid claim of the '777 patent;

iv. That the Court declare, adjudge and decree that the '777 patent is unenforceable;

v. That the Court declare this to be an exceptional case under 35 U.S.C. § 285 and award SPI Pharma its costs, disbursements and reasonable attorneys' fees incurred in this action;

vi. That the Court award such other and further relief as the Court may deem just and proper under the circumstances.

JURY TRIAL DEMAND

30. Defendant SPI Pharma demands a trial by jury on all issues so triable.

YOUNG CONAWAY STARGATT
& TAYLOR, LLP

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OF COUNSEL:
Brian P. Murphy, Esq.
Daniel P. Murphy, Esq.
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(212) 309-6000

Dated: December 28, 2007

EXHIBIT B

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

ROQUETTE FRERES, Plaintiff, v. SPI PHARMA, INC., DRYTEC LTD., ANHYDRO U.K. LTD., DRYTEC CONTRACT PROCESSING LTD. and ANHYDRO HOLDING A/S, Defendants.	)	C.A. No. 06-540-(***) **DEMAND FOR JURY TRIAL**

DEFENDANT SPI PHARMA, INC.'S FIRST AMENDED ANSWER, DEFENSES AND COUNTERCLAIMS IN RESPONSE TO PLAINTIFF'S SECOND AMENDED COMPLAINT

Defendant, SPI Pharma, Inc. ("SPI Pharma"), by and through the undersigned counsel requests trial by jury on all issues so triable, and amends its Answers to the corresponding paragraphs of the Second Amended Complaint ("Complaint") of Plaintiff, Roquette Freres ("Plaintiff" or "Roquette"), as follows:

JURISDICTION AND VENUE

1. SPI Pharma admits that the complaint, on its face, alleges a cause of action for patent infringement arising under Title 35 of the United States Code, that jurisdiction of this Court is conferred by 28 U.S.C. § 1338(a), that venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b) and that it has a principal place of business in the District of

Delaware. SPI Pharma denies the remaining allegations of Paragraph 1 of the Complaint and specifically denies that it has engaged in infringing activities within this District.

BACKGROUND AND PARTIES

2. SPI Pharma admits the allegations of Paragraph 2 of the Complaint.

3. SPI Pharma admits that U.S. Patent No. 5,573,777 (the " '777 patent"), on its face, lists Plaintiff as the assignee, and that a copy of the '777 patent is attached to the Complaint as Exhibit A. SPI Pharma otherwise has insufficient knowledge or information upon which to form a belief as to the truth of the remaining allegations and therefore denies them.

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INFRINGEMENT OF THE '777 PATENT

8. SPI Pharma denies the allegations contained in Paragraph 8 of the Complaint.

9. SPI Pharma denies the allegations contained in Paragraph 9 of the Complaint.

10. SPI Pharma denies the allegations contained in Paragraph 10 of the Complaint.

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DEFENSES and AFFIRMATIVE DEFENSES

SPI Pharma asserts the following defenses and affirmative defenses against the allegations made by Plaintiff in the Complaint. SPI Pharma hereby reserves the right to amend its First Amended Answer and plead any additional defenses and/or counterclaims that become available or known as this action proceeds, including, but not limited to, those defenses that become known to SPI Pharma through discovery.

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18. SPI Pharma does not infringe any valid claim of the '777 patent, nor does SPI Pharma contribute to or induce infringement of any valid claim of the '777 patent.

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COUNTERCLAIMS

For its counterclaims against Plaintiff, SPI Pharma alleges as follows:

Nature of the Counterclaim

23. The counterclaims herein are made under 28 U.S.C. §§ 2201 and 2202 for a declaratory judgment of invalidity and non-infringement of the '777 patent.

24. This Court has jurisdiction over the subject matter of these counterclaims under 28 U.S.C. §§ 1331 and 1338 in that the actions arise under the Patent Laws of the United States, Title 35, United States Code. Venue is proper under 28 U.S.C. § 1391 and Plaintiff has submitted itself to the jurisdiction of this Court.

25. Plaintiff and Counterclaim-Defendant Roquette is a corporation formed under the laws of France with its principal place of business at 62080 Lestrem, Cedex, France.

26. Defendant and Counterclaim-Plaintiff SPI Pharma is a Delaware corporation with its principal place of business at 321 Cherry Lane, New Castle, Delaware.

27. An actual and justiciable controversy exists between Plaintiff and SPI Pharma concerning the invalidity and non-infringement of the '777 patent.

First Counterclaim

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Applicants Misrepresented the Content of the Prior Art

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32. For example, the '777 patent specification describes prior art reference Japanese Patent Application 61-85331 ("JP 61-85331"), which is directed toward a method for preparing a mixture of D-mannitol with starch hydrolysate, by spray-drying, to obtain an excipient for tabletting. In describing JP 61-85331, the '777 patent specification states: "It emerges from this document that, with less than 5% starch hydrolysate, the excipient obtained according to this process,...always has an excessively high content of particles with a size of less than 200 mesh (75 microns)." (emphasis added).

33. JP 61-85331 contains data that include, *inter alia*, particle size distribution percentages for four samples of the excipient obtained according to the method described therein. These data show that the samples had only between 4-6% of particles with a size of less than 200 mesh (75 microns) -- not an "excessively high content" as Applicants represented to the PTO in the '777 patent specification.

34. Inventors Serpelloni and Boonaert testified at deposition that they did not review JP-6185530, despite making factual assertions concerning that reference in the '777 patent specification.

35. The '777 patent specification also describes prior art reference Japanese Patent Application 61-85330 ("JP 61-85330"), which is directed toward a method for preparing D-mannitol (without starch hydrolysate), by spray drying, to obtain an excipient for tabletting. In describing JP 61-85330, the '777 patent specification states: "It appears that the products obtained under these conditions contain, in the manner of the control products, more than 50% of

particles with a size of less than 200 mesh (75 microns), which is harmful to a correct flow of the products." (emphasis added).

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38. JP 55-36646 does not contain any data reflecting particle size distribution percentages nor statements concerning the percentage of fine particles obtained by the process described therein.

39. Inventor Boonaert testified at deposition that he did not verify the statement in the '777 patent specification concerning JP 55-36646.

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above, always very low, so much so that the mean diameter of the particles is between 50 and 75 microns." (emphasis added).

41. The '146 patent does not contain any data or statements relating to the mean diameter of the particles obtained according to the process described therein.

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Applicants Presented Misleading, Incomplete and Unsupported Data in the '777 Patent Specification

43. Applicants provide two tables of data in the '777 patent specification that purport to compare functional properties of mannitol obtained in accordance with the alleged invention to products obtained in accordance with the prior art ("prior art products"). See Table in Example 2, Col. 11 and 12, lns. 1-40 (hereinafter "Table 1") and Table in Example 3, Col. 12, lns. 46-53 (hereinafter "Table 2").

44. Table 1 provides data for five comparator prior art products. Only one of the comparators is a spray-dried mannitol. The other four comparators are mannitol products produced by means other than spray drying. Applicants did not provide any data in Table 1 for closer prior art comparators such as mannitol obtained in accordance with JP-55-36646 or the '146 patent, which are both directed to spray-dried mannitol, despite being aware of these references and describing them in an earlier portion of the '777 patent specification. (See Paragraphs 37 and 40, *supra*).

45. Inventor Serpelloni testified at deposition that he did not conduct any of the tests resulting in the data provided in Table 1, nor did he ever see any documentation to support those

data. With respect to Table 1, inventor Boonaert testified at deposition that "the only possible test that we could carry out in production [dept] was density and the diameter of particles," but he never claimed that he actually performed those test. To date, Roquette has not produced any documents that record the data provided in Table 1.

46. On its face, Table 1 data are inconsistent, incomplete and/or contradictory. For example, while some data show a range of values, suggesting that Applicants performed multiple experiments, others show only a single value, suggesting that Applicants performed only a single experiment. If Applicants performed multiple experiments, then they intentionally omitted data in those instances where they reported a single data point rather than a range. Alternatively, if Applicants performed a single experiment, then where they reported a range of values, they intentionally used data from a different source without proper attribution or notice to the PTO.

47. In addition, Table 1 purports to provide data for the "Commercial Product" produced according to French Patent No. 2,572,045 ("the '045 patent"), a prior art patent issued to Serpelloni and assigned to Roquette. However, Serpelloni testified at deposition that Roquette never made a commercial product according to the process in the '045 patent and that he did not know the identity of the product that was allegedly tested.

48. Table 2 in the '777 patent specification compares the compression force of mannitol made in accordance with the alleged invention to the compression force of granulated sucrose, lactose monohydrate in the α form, lactose monohydrate in the a form (atomized), and anhydrous lactose in the α form. Table 2, Col. 12, lns. 46-67. Applicants do not compare mannitol made in accordance with the alleged invention with any prior art mannitol product, even though such products were readily available. The data in Table 2 purport to show that the "product according to the invention permits the advantageous obtention [sic] of harder tablets

than with the different compressible products based on lactose or on sucrose currently utilized in this application." '777 patent, Col. 12, lns. 54-57.

49. Data for compression force for prior art mannitol products was readily available to Applicants because Roquette, and inventor Serpelloni in particular, had conducted such tests during manufacture of its own prior art granular mannitol product. Those data show that there is no difference between the alleged invention and prior art mannitol with respect to compression force.

50. The data and comparisons in Table 2 are misleading because they do not utilize the closest prior art. Applicants intentionally withheld information material to patentability with respect to compression force in order to exaggerate the alleged benefits of their invention to the PTO.

51. The foregoing facts and circumstances set forth in this Third Counterclaim constitute inequitable conduct on the part of Applicants rendering the '777 patent unenforceable.

WHEREFORE, Defendant and Counterclaim-Plaintiff SPI Pharma asks that the Court enter an Order against Plaintiff and Counterclaim-Defendant Roquette as follows:

i. That the Complaint be dismissed with prejudice, that Roquette take nothing by way of its Complaint and that SPI Pharma be awarded judgment in its favor on the claims in Roquette's Complaint;

ii. That the Court declare, adjudge and decree that the claims of the '777 patent are invalid;

iii. That the Court declare, adjudge and decree that SPI Pharma has not infringed and does not infringe any valid claim of the '777 patent;

iv. That the Court declare, adjudge and decree that the '777 patent is unenforceable;

v. That the Court declare this to be an exceptional case under 35 U.S.C. § 285 and award SPI Pharma its costs, disbursements and reasonable attorneys' fees incurred in this action;

vi. That the Court award such other and further relief as the Court may deem just and proper under the circumstances.

JURY TRIAL DEMAND

30. Defendant SPI Pharma demands a trial by jury on all issues so triable.

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